

REMARKS

Claims 2, 3, 6, 14, 15, 18, 21 and 22 have been canceled, and Claims 1, 4, 5 and 7 have been amended. Support for the amended claims is found throughout the application as originally filed, for example, at page 6, lines 9-15. This Amendment adds no new matter. Further remarks are set forth below with reference to the numbered paragraphs of the Office Action.

Paragraph 5. Related Applications

The Related Applications Paragraph has been updated to reflect the current status of the cited applications.

Paragraph 6. Abstract of the Disclosure

An Abstract of the Disclosure on a separate sheet is provided herewith.

Paragraph 8. Rejection of Claims 1-7 and 18-22 Under 35 U.S.C. § 112, First Paragraph

Claims 1-7 and 18-22 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner states that a deposit of a cell line that produces monoclonal antibody M-T412 or cell line producing c128 under the terms of the Budapest Treaty is required.

Applicants' will make a suitable biological deposit under the Budapest Treaty before payment of the Issue Fee in accordance with 37 C.F.R. § 1.809(c), if claims are indicated as being allowable. (See, also, MPEP § 2406.)

Paragraph 10. Rejection of Claims 1-6 under 35 U.S.C. § 102(b) or § 103(a)

Claims 1-6 are rejected under 35 U.S.C. § 102(b) as being anticipated by or in the alternative under 35 U.S.C. § 103(a) as being obvious over Oi *et al.* as evidenced by Taylor *et al.* The Examiner states that Oi *et al.* teaches a chimeric anti-CD4 antibody based on a murine anti-CD4 antibody and that Taylor *et al.* indicates that CD4 probably contains 5-7 epitopes. The Examiner further states that it is reasonable to conclude that the claimed antibody binds the same epitope as the chimeric antibody disclosed in Oi *et al.*, and attempts to shift the burden to

Applicants to show a nonobvious distinction between the claimed immunoglobulins and antigen-binding fragments and the prior art.

Claims 2, 3 and 6 have been cancelled. Claims 1, 4 and 5 have been amended to recite that the chimeric antibody or chimeric antigen binding fragment comprises the variable region of monoclonal antibody M-T412. Neither Oi *et al.* nor Taylor *et al.* disclose a chimeric antibody or antigen binding fragment comprising the variable region of monoclonal antibody M-T412. Therefore, Claims 1, 4 and 5 are not anticipated.

To render a claimed invention *prima facie* obvious, there must be some suggestion or motivation to modify or combine the teachings of the prior art and a reasonable expectation of success in arriving at the claimed invention. M.P.E.P. § 2143 at 2100-124 (8th ed. Rev. 1, Feb. 2003). Also, the prior art must teach or suggest all of the claim limitations. *In re Royka*, 180 USPQ 580 (CCPA 1974); M.P.E.P. §§ 2143 at 2100-124, 2143.03 at 2100-128 (8th ed. Rev. 1, Feb. 2003).

The claimed invention is not obvious, because neither Oi *et al.* nor Taylor *et al.* teaches or suggests monoclonal antibody M-T412 or the variable region of monoclonal antibody M-T412, or directs the person of ordinary skill in the art to the particular variable region of monoclonal antibody M-T412. Therefore, the combined teachings of Oi *et al.* and Taylor *et al.* fail to provide the requisite suggestion or motivation to produce the claimed chimeric immunoglobulins or antigen binding fragments, which comprise a particular variable region. Moreover, the prior art fails to teach or suggest all of the claim limitations because neither Oi *et al.* nor Taylor *et al.* teaches or suggests monoclonal antibody M-T412 or the variable region of monoclonal antibody M-T412, or directs the person of ordinary skill in the art to the variable region of monoclonal antibody M-T412.

The invention of Claims 1, 4 and 5 is not obvious because the references cited by the Examiner fail to provide the requisite suggestion or motivation to produce the claimed chimeric immunoglobulins or antigen binding fragments, and do not teach or suggest all of the claim limitations.

Withdrawal of the rejections under 35 U.S.C. §§ 102 and 103 is requested.

The Examiner also attempted to shift the burden to Applicants to show a nonobvious distinction over the prior art under In re Best. However, as amended, the claims recite that the chimeric immunoglobulins or antigen-binding fragments comprise the particular variable region of monoclonal antibody M-T412. This structural feature is novel and nonobvious, and distinguishes the claimed subject matter from the antibody disclosed in Oi *et al.* for the reasons stated above.

Paragraph 11. Rejection of Claims 1-7, 19 and 20 Under 35 U.S.C. § 103(a)

Claims 1-7, 19 and 20 are rejected under 35 U.S.C. § 103(a) as being obvious over Oi *et al.* in view of Landau *et al.* or Taylor *et al.* or Weissenhorn *et al.* The examiner states that Oi *et al.* teaches a chimeric anti-CD4 antibody based on a murine anti-CD4 antibody and that Landau *et al.*, Weissenhorn *et al.* and Taylor *et al.* each teach a panel of murine monoclonal anti-CD4 antibodies that bind distinct epitopes on CD4. The Examiner further states that Taylor *et al.* indicates that CD4 probably contains 5-7 epitopes. The Examiner concludes that it would have been obvious to produce a chimeric version of any of the disclosed antibodies using the techniques taught by Oi *et al.*

Claims 2, 3 and 6 have been cancelled. Claims 1, 4 and 5 have been amended to recite that the chimeric antibody or chimeric antigen binding fragment comprises the variable region of monoclonal antibody M-T412.

To render a claimed invention *prima facie* obvious, there must be some suggestion or motivation to modify or combine the teachings of the prior art and a reasonable expectation of success in arriving at the claimed invention. M.P.E.P. § 2143 at 2100-124 (8th ed. Rev. 1, Feb. 2003). Also, the prior art must teach or suggest all of the claim limitations. In re Royka, 180 USPQ 580 (CCPA 1974); M.P.E.P. §§ 2143 at 2100-124, 2143.03 at 2100-128 (8th ed. Rev. 1, Feb. 2003).

The claimed invention is not obvious, because none of Oi *et al.*, Landau *et al.*, Taylor *et al.* and Weissenhorn *et al.*, alone or in any combination, teaches or suggests monoclonal antibody M-T412 or the variable region of monoclonal antibody M-T412, or directs the person of ordinary skill in the art to the particular variable region of monoclonal antibody M-T412. Therefore, the

combined teachings of Oi *et al.*, Landau *et al.*, Taylor *et al.* and Weissenhorn *et al.* fail to provide the requisite suggestion or motivation to produce the claimed chimeric immunoglobulins or antigen binding fragments, which comprise a particular variable region. Moreover, the cited prior art fails to teach or suggest all of the claim limitations because none of Oi *et al.*, Landau *et al.*, Taylor *et al.* and Weissenhorn *et al.* teaches or suggests monoclonal antibody M-T412 or the variable region of monoclonal antibody M-T412, or directs the person of ordinary skill in the art to the variable region of monoclonal antibody M-T412.

Therefore, the invention of Claims 1, 4, 5, 19 and 20 is not obvious because the references cited by the Examiner fail to provide the requisite suggestion or motivation to produce the claimed chimeric immunoglobulins or antigen binding fragments, and do not teach or suggest all of the claim limitations. Withdrawal of the rejection is requested.

Request for Rejoinder

Non-elected Claims 13, 16 and 17 are drawn to a method of therapy comprising administering a chimeric immunoglobulin or chimeric antigen binding fragment of Claim 1. Therefore, if product Claim 1 is found to be allowable, then method Claims 13, 16 and 17 should also be allowable. Applicants request, pursuant to U.S. Patent Office practice (MPEP § 821.04), that Claims 13, 16 and 17 be rejoined if Claim 1 is found to be allowable.

Information Disclosure Statement

A Supplemental Information Disclosure Statement (SIDS) is being filed concurrently herewith. Acknowledgment of consideration of the information provided in the SIDS is requested in the next office communication.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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Dated: *December 3, 2003*